REMARKS

Claims 1, 3, 11, and 21 stand rejected. Claims 4 and 18 have been deemed free of the art of record and allowable. Applicant acknowledges that certain grounds of objection/rejection have been withdrawn or mooted. The present response addresses only the remaining grounds of rejection and any new grounds of rejection but maintains all previous arguments.

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1, 3, and 11 were rejected under 35 U.S.C. 112, ¶1, for non-enablement. The Examiner has maintained this rejection on grounds that there is no showing of variability of the polypeptide in affording protection against S. pneumoniae.

In effect, the Examiner argues that the specification does not show that polypeptides of variable sequence can act to elicit antibodies against SEQ ID NO: 8. The Examiner quotes from the specification at page 13, lines 24-30, as being directed to the ability of fragments to elicit an antibody against native polypeptide but failing to show the use of polypeptides with the recited percent identity.

In response, Applicants contend that claim 1 is drawn to an immunogenic composition comprising an isolated polypeptide with at least 80% identity to SEQ ID NO: 8, in a carrier and able to elicit antibodies against the polypeptide of SEQ ID NO: 8 when administered to a mammal.

In support of the foregoing, Applicants direct the Examiner's attention to page 10, lines 23-26, which states that Applicant's vaccines

[Application Excerpt 1]

> also comprise a polypeptide, including immunogenic fragments thereof, having an amino acid sequence at least 65% identical, preferably 80% identical, most preferably 95% identical, and ideally 100% identical to the amino acid sequence of SEQ ID NO:8.

Thus, the polypeptides of Applicants' vaccines would include polypeptides having the recited percent identities. Such polypeptides represent the "isolated polypeptide" of claim 1 and these may be in a carrier. The remaining element of claim 1 is use of such a polypeptide to raise an antibody against Sp130 (SEQ ID NO: 8) when the isolated polypeptide is given to a mammal. The statement from the specification (recited in the rejection and originally offered by Applicants in the previous amendment) states:

[Application Excerpt 2]

> Antibodies generated against a polypeptide vaccine corresponding to a sequence of the present invention can be obtained by direct injection of the polypeptide into an animal or by administering the polypeptide to an animal, preferably a nonhuman. The antibody so obtained will then bind the polypeptide itself. In this manner, even a sequence encoding only a fragment of the polypeptide can be used to generate antibodies binding the whole native polypeptide. [application at page 13, lines 24-30, emphasis added]

Applicants believe that the Examiner reads the above statement too narrowly, apparently interpreting this portion of Applicants' disclosure as supporting only use of a fragment of SP130 to elicit antibodies against the polypeptide. However, the first sentence describes use of a polypeptide of the invention (such as one with 80% identity to SEQ ID NO: 8) to generate antibodies (because Applicants state [in Excerpt 1] that their disclosed vaccines would comprise a polypeptide having such sequence homology). Thus, "polypeptide vaccine" means one containing a variable polypeptide (e.g., having at least 80% identity). Further, Excerpt 2 (at line 5 thereof) states "in this manner" fragments can be used to elicit antibodies that bind the "whole native

polypeptide" so that fragments are simply used in the same way as the polypeptides of variable homology to elicit antibodies against the native polypeptide.

As used by Applicants, the term "native polypeptide" simply refers to the polypeptide with the amino acid sequence of SEQ ID NO: 8, as stated in the application starting at page 9, line 30:

> [Application Excerpt 3]
>
> Such fragments, derivatives and analogs must have sufficient similarity to the polypeptides SEQ ID NOS: 6 and 8, so that activity of the native polypeptide is retained. [emphasis added]

Thus, SEQ ID NO: 8 itself is what Applicants mean by a "native polypeptide" within the claims (because that is the sequence found in the organism).

Further, the application discloses (at page 16, line 29, to page 17, line 1) that:

> [Application Excerpt 4]
>
> the polypeptides of the present invention can be used as immunogens to stimulate the production of antibodies for use in passive immunotherapy, for use as diagnostic reagents, and for use as reagents in other processes such as affinity chromatography. [emphasis added]

Now, the polypeptides of the invention are those polypeptides with the recited percent identities. Per Excerpt 4, *supra*, these are useful as immunogens to elicit antibodies for diagnostic purposes (i.e., "as diagnostic reagents" for detecting the presence of the pneumococcal organism), which organism necessarily possesses the native polypeptide (i.e., SEQ ID NO: 8). Thus, to be used as a diagnostic reagent, the immunogen (e.g., a polypeptide of 80% identity) must elicit production of an antibody against the native polypeptide (i.e., SEQ ID NO: 8). Otherwise, the elicited antibody could not be used for diagnostic purposes.

In addition, Applicants note that sera raised in human patients against a spectrum of pneumococcal organisms was able to bind to SP130 polypeptide (SEQ ID NO: 8) as shown in the Western blot of Figure 3. However, SEQ ID NO: 8 is from only one strain (Norway serotype 4) yet reacts with antibodies raised against heterologous strains (see application at page 4, lines 17-19) that may have varying se4quence homologies to SP130. Consequently, polypeptides (present in said heterologous strains) of varying sequence homology to SEQ ID NO: 8 would be expected to raise antibodies that bind to SP130 (SEQ ID NO: 8).

Applicants have also amended claim 11 to depend only on claim 4 and request that claim 13, directed to a method of use of the composition of claim 11, be rejoined.

In addition, Applicants have amended claim 21 to recite a vaccine comprising fragments of SEQ ID NO: 8 as an independent claim. Applicants note that all of the recited fragments comprise amino acids 650-773 of SEQ ID NO: 8 and therefor are expected to possess protective activity.

Applicants believe that these amendments remove this ground of rejection.

Rejection Under 35 U.S.C. §112, First Paragraph (New Matter)

Claims 1, 3 and 11 were rejected under 35 U.S.C. §112, first paragraph, as reciting new matter.

The Examiner's argument appears to be directed to much the same contentions as stated above for the showing of lack of support in the specification. Applicants believe that the above arguments on that point are equally applicable to this new matter rejection. In view of Applicants' above comments on support in the specification for the breadth of the claims, Applicants believe that no new matter is presented.

Further, using the methods disclosed in the Examples of the application, it is readily determined which polypeptides are able to meet the claim limitations since it is well known how to determine percent identity (see, for example, application at page 6, starting at line 18, for Applicants' definition of percent identity), while binding to an antibody that binds the polypeptide of SEQ ID NO: 8 is also readily determined. Such polypeptide will have the intended activity. Because this limitation is fully supported in the specification (as already described in detail above), Applicants urge that no new matter has been added by way of the claim amendments.

In view of the foregoing remarks, Applicants believe that this ground of rejection has been overcome.

Rejection Under 35 U.S.C. §112, First Paragraph (Scope of Enablement)

Claim 21 was rejected under 35 U.S.C. §112, first paragraph, for lack of enablement in that the specification is enabling for an immunogenic composition containing the recited fragments but not for a vaccine containing said fragments.

In response, Applicants have amended claim 21 delete reference to "vaccine" and instead recite an "immunogenic composition" comprising said fragments. In addition, Applicants have added the fragment consisting of residues 620-773 of SEQ ID NO: 8 as also recited in the application at page 12, line 23).

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 1, 3, 11 and 21 were rejected under 35 U.S.C. 112, ¶2, as indefinite.

Claim 1 was rejected as indefinite for recitation of the phrase: "polypeptide consisting of the sequence." Applicants fail to find this phrase in claim 1. Claim 1 is

instead drawn to a "composition comprising an isolated polypeptide having an amino acid sequence..." but Applicants have followed the Examiner's suggestion and amended this to recite "polypeptide consisting of the amino acid sequence...."

Claim 21 was rejected as vague and indefinite for reciting "selected from residues...." In response, Applicants have amended claim 21 to recite "selected from amino acid residues" in line with the Examiner's suggestion.

Applicants believe that these amendments make said claims sufficiently clear so as to overcome the indicated ground of rejection.

Claim Objection

In response to the objection to claim 1 for use of a comma after "polypeptide" in line 2, this claim has been amended to delete said comma.

Further Amendment

In addition, although claim 18 has been found free of the art of record and allowable, Applicants have further amended this claim to replace "having" with "consisting of" for clarity purposes.

Request for Rejoinder

Applicants request that claims 12 and 13 be, currently withdrawn from consideration, be rejoined in view of Applicants' amendment of claim 12 to depend only from claim 4, which makes this claim a claim to the use of the polypeptide present as

the active ingredient of the immunogenic composition of claim 4 and so should require little or no additional examination. In addition, claim 13 is drawn to the method of use of the composition of claim 4 because it depends from amended claim 11.

In view of the amendments made herein, and the above remarks, Applicants urge that these method claims should be rejoined and allowed along with the claims to the polypeptide or composition used in said methods since they now incorporate all of the limitations of the product claims (see MPEP 806.05(h)).

No fee is believed due in filing this response. If any fee is due, the Commissioner is authorized to charge any and all such fees to Deposit Account No. 03-0678.

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